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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/614,452	11/16/90	LEE	S 81754/1.3C

EXAMINER
ALLEN, M

ART UNIT	PAPER NUMBER
1812	10

DATE MAILED: 01/11/93

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 10/5/92 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-21 are pending in the application.
   Of the above, claims 4-10, 17, 18 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-3, 11-16, 19-21 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

The rejection of claims 1, 3, and 11-15 as provisionally rejected under 35 U.S.C. § 101 over claims 1, 3, and 11-15 of copending application Serial No. 07/538,372 is withdrawn as application 07/538,372 has been abandoned.

The rejection of claim 2 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of copending application Serial No. 07/538,372 is withdrawn as application 07/538,372 has been abandoned.

Applicant's arguments filed 5 October 1992 have been fully considered but they are not deemed to be fully persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 11-16, and 19-21 are rejected under 35 U.S.C. § 101 because the claimed subject matter lacks patentable utility.

Claims 1-3 are drawn to DNA segments encoding a mammalian GDF-1 protein. Although useful properties are alleged based upon the similarity of the GDF-1 amino acid sequence to the TGF-β family, there is no evidence of record that this DNA sequence encodes a biologically useful protein possessing any particular properties. (See specification pages 12-14.) The utility of the vectors and transformed host cells of claims 11-14 and the method of claim 15 turns on the utility of the sequences of claims 1-3.

Claim 16 is drawn to a DNA segment encoding a mammalian UOG-1 protein. There is no utility alleged for the UOG-1 DNA sequence other than it <u>may</u> be a receptor and <u>may</u> be involved with the biological activity for GDF-1. (See page 15, lines 9-29.) The utility of the vectors and transformed host cells of claims

19-20 and the method of claim 21 turns on the utility of the sequences of claim 16. The specification presumes a utility that has not been established.

Applicant argues that the alleged utility of the GDF-1 and UOG-1 proteins encoded by the claimed DNA sequences is believable on its face. The examiner disagrees. The disclosed utilities for the GDF-1 protein as a diagnostic tool for screening and potential utilities as therapeutic agents are not supported. There is no evidence of any disease state that can be treated with this protein nor any tumors, genetic diseases, or developmental anomalies that applicant has associated with this gene or protein. There is no evidence of any kind that UOG-1 has any useful biological activity that would meet the burden of a patentable utility.

Applicant argues that the similarity of the GDF-1 sequence to the TGF-ß family is sound basis for the asserted utility. Structural similarity is not sufficient to establish utility. Furthermore, the similarities only range from 26-52% on the amino acid level. In order to meet the burden of patentable utility, a specific benefit must exist in a currently available form. Use for further research and determination of useful properties is not a practical utility. (See for example, Brenner v. Manson, 148 USPQ 689 (1966)). Applicant has not provided any reasoning supporting the allegation that the utility of UOG-1 is believable on its face.

The rejection of claims 1-3 and 11-15 under 35 U.S.C. § 102(a) as being anticipated by Derynck et al. (U.S. Patent No. 4,886,747) is withdrawn due to amendment of the claims.

The rejection of claims 1-2 and 11 under 35 U.S.C. § 102(b) as being anticipated by Weeks et al. is withdrawn due to amendment of the claims.

The rejection of claims 1-3 and 11-15 under 35 U.S.C. § 102(e) as being anticipated by Wang et al. (U.S. Patent No. 5,013,649) is withdrawn due to amendment of the claims.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description and enabling disclosure.

Applicant has failed to disclose how to use the claimed invention. Useful properties for GDF-1 are alleged based upon the similarity of the amino acid sequence encoded to the TGF-β family; however, there is no evidence of record that this DNA sequence encodes a biologically useful protein possessing any particular properties and in the absence of such a showing it is

unknown how to use this DNA sequence, the vectors, host cells, or method of producing GDF-1.

There is no description of how to use the DNA sequence encoding UOG-1, the vectors, host cells, or method of producing associated with this UOG-1 encoding sequence in the specification.

See also remarks above with respect to the rejection of claims 1-3, 11-16, and 19-21 under 35 U.S.C. § 101.

While expression of GDF-1 is described on page 6 in the description of figure 9, insufficient details are presented to determine what was performed. It does not appear that the protein was isolated as set forth in the method. There does not appear to be a further discussion of figure 9 and the recombinant production of GDF-1 in the specification. It is deemed to be unpredictable whether the protein could be successfully produced recombinantly in the absence of a clear description of its production which the specification lacks. As such, the method of claim 15 is not sufficiently described nor enabled.

The method of claim 21 is clearly prophetic. There is no description of producing vectors, transformed host cells, or producing the protein encoded by the DNA sequence recombinantly. It is deemed to be unpredictable whether the protein could be successfully produced recombinantly.

In addition, it would constitute undue experimentation to produce functionally equivalent variations of GDF-1 and UOG-1 as

set forth in claims 15 and 21 respectively, when it is unknown what DNA sequences encode functional equivalents. Because there is no known biological activity for either protein, there can be no assays for determining biological activities for functionally equivalent proteins. It is noted that none are set forth in the specification.

Claims 1-3, 11-16, and 19-21 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 2, 11, 15, and 19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite for failing to indicate whether the DNA sequence encoding the GDF-1 protein is intended to be claimed (i.e. the coding region) or the entire sequence of Figure 2, 11A, or 11B. It is noted that the sequence of figures 11A and 11B include the sequences for UOG-1.

Claim 15 is indefinite in reciting "segment". There must be direct and clear antecedent basis. There is no clear antecedent basis for this term in the preamble of the claim or claim 12 although there appears to be basis in claim 11 upon which claim 12 depends. Claim 15 could be amended in approximately the following manner to obviate this rejection: "A method of

producing a recombinant GDF-1 protein comprising culturing the host cell of claim 12 under conditions such that said GDF-1 protein is produced and isolating said GDF-1 protein". Claim 21 should be amended accordingly for the same reasons.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(l). Correction of the following is required: Vectors containing DNA sequences encoding UOG-1 and transformed host cells containing these vectors do not appear to be present in the specification. The methods of claims 15 and 21 as written do not appear to be present in the specification. Applicant is required to correct this and is cautioned against introducing new matter into the specification.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1

Fax Center number is (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (703) 308-0666.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ROBERT J. HILL, JR.
SUPERVISORY PATENT EXAMINER
GROUP 1800